

REMARKS

Claims 46, 54-77, and 80-101 are now pending in the case, new claims 84-101 having been added by the above amendment. The amendments to claims 56-59, 64, 77, 80 and 81 merely alter the wording slightly as requested by the Examiner, and do not change the scope of the claims. New claims 84, 85, 90, and 91 are supported in the specification, e.g., at page 4, lines 3, 7 and 8. New claims 86 and 92 are supported, e.g., at page 4, lines 5, 8, 22-23, and 25. New claims 87 and 93 are supported, e.g., at page 4, lines 5, 9, and 25. New claims 88 and 94 are supported, e.g., at page 4, lines 5, 8, and 25. New claims 89 and 95 are supported, e.g., at page 4, lines 5, 8, and 25. New claims 96-101 are supported, e.g., at page 3, lines 15-16, and in original claims 14-16. No new matter has been added.

On page 1 of the Office Action, the Examiner requested that Applicants amend the title of the invention to be more descriptive. Applicants submit that the new title introduced by the above amendment fully describes the presently claimed invention, and adds no new matter.

On page 4 of the Office Action, the Examiner requested that Applicants update the status of the continuation data referred to in the specification. Applicants respectfully point out that this application was filed and accepted under 35 USC § 371. Accordingly, there are no continuation data referred to in the specification, and nothing needs to be updated.

Rejections under 35 USC § 112, second paragraph

On pages 2-3 of the Office Action, claims 56-59, 60, 64, 77 and 80-81 were rejected as being indefinite, for various reasons. The above amendment puts claims 56, 77, and 80-81 into Markush format, as requested by the Examiner. Claim 59 is also now in this format. Claims 56 and 57 have been reworded to clarify the nature of the propellant mixture. The agent "TA-2005" no longer appears in the list of medicaments in claim 60. In claim 64, the listed ingredients are now referred to more generically as "substances" rather than "pharmaceutically active agents." As Applicants have met all of the objections raised by the Examiner under the second paragraph of 112, withdrawal of the rejection is respectfully requested.

Rejections under 35 USC § 112, first paragraph

On page 2 of the Office Action, the Examiner rejected all of the claims for lack of enablement. The entire text of that rejection is set forth here:

Claims 46, 54-77 and 80-83 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for decyl glucoside and dodecyl maltoside, does not reasonably provide enablement for all alkyl saccharides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. There is no basis in the specification to extrapolate these two specific alkyl saccharides to encompass the infinite number of compounds that may be classified under the broad term "alkyl saccharide." (emphasis in original)

Applicants traverse. According to the MPEP at 2164.04,

In order to make a rejection [for lack of enablement], the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

Here, the Examiner has not even come close to meeting this burden. Not only is there no objective evidence on record to support the Office Action's conclusory statement that the specification does not enable one of ordinary skill to use the invention, there is not even any reasoning other than another conclusory statement that "There is no basis in the specification to extrapolate these two specific alkyl saccharides to encompass the infinite number of compounds that may be classified under the broad term 'alkyl saccharide.'" Applicants fail to see how use of a term that encompasses a broad but clearly defined group of compounds can be, in and of itself, a basis for lack of enablement. The enablement requirement of § 112, first paragraph, requires that the specification teach how to make and use the invention. It does not require that the specification list all, or even any, of the compounds that are encompassed by a broad term.

The Examiner has not suggested that one of ordinary skill, upon reading the specification, would fail to understand how to make the claimed formulations containing any alkyl saccharide. Rather, the Examiner offers the theory that, because the term "alkyl saccharide" is fairly broad, one of ordinary skill would not know how to use any formulation where the surfactant is defined as an "alkyl saccharide". Applicants do not understand the basis for this theory. As noted in the background section of the specification, and as the Examiner must realize, aerosol formulations in general are widely used for treating respiratory and nasal disorders. The present specification teaches generally that all of the disclosed formulations (including but not limited to those utilizing alkyl saccharides as surfactants) can be used to deliver aerosolized medicaments. Beyond providing a description of how a patient or doctor would administer aerosolized medicaments, which the Examiner must agree would be superfluous in view of the knowledge in the art, it is unclear what more enabling how-to-use description could be provided for the claimed formulations. Indeed, the Office Action explicitly acknowledges that the specification adequately enables use of certain of the claimed formulations: those that employ either decyl glucoside or dodecyl maltoside as surfactant.¹ Since the specification teaches that all alkyl saccharides would be used in the same way as these two specific ones (see page 3, lines 15-16, and page 2, lines 9-19), the enablement provided for decyl glucoside and dodecyl maltoside applies equally to all alkyl saccharides. The Office Action has certainly not provided any reason to believe otherwise. Nor has the Examiner even alleged (much less provided evidence or reasoning) that alkyl saccharides other than decyl glucoside and dodecyl maltoside are unlikely to function as claimed. The MPEP at 2164.04 addresses this issue by quoting from two court opinions:

As stated by the [*In re Marzocchi*] court, "it is incumbent upon the Patent Office whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Otherwise, there would be no need for the applicant to go to the trouble and expense of

¹ In this regard, Applicants query why claims 55 and 80, which are limited to embodiments that the Office Action acknowledges are fully enabled, were included in this enablement rejection.

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supporting his presumptively accurate disclosure." [439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)].

According to *In re Bowen*, 492 F.2d 859, 862-63, 181 USPQ 48, 51 (CCPA 1974), the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments.

In view of the above, Applicants respectfully request withdrawal of the rejections and allowance of all of the claims.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a \$90 check for excess claim fees and a \$920 check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

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Janis K. Fraser, Ph.D., J.D.
Reg. No. 34,819

Fish & Richardson P.C.
225 Franklin Street
Boston, Massachusetts 02110-2804
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

Version with markings to show changes made

In the title

Please amend the title on page 1:

Aerosol Drug Formulations Containing Hydrofluoroalkanes and Alkyl Saccharides

In the claims:

Please amend claims 57-60, 64, 77, and 80-81 as follows:

56. (Amended) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the [propellant] formulation comprises a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227), or 1,1-difluoroethane (P152a).

57. (Amended) A pharmaceutical aerosol formulation as claimed in claim 56, wherein the [propellant] formulation comprises a propellant mixture comprising 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

58. (Amended) A pharmaceutical aerosol formulation as claimed in claim 57, wherein the [propellant] formulation comprises a density-matched propellant mixture of 1,1,1,2-tetrafluoroethane (P134a) and 1,1,1,2,3,3,3-heptafluoropropane (P227).

59. (Amended) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the medicament is selected from the group consisting of a β 2-adrenoreceptor agonist, an anticholinergic bronchodilator, [or] and a glucocorticosteroid.

60. (Amended) A pharmaceutical aerosol formulation as claimed in claim 46, wherein the medicament is selected from the group consisting of salbutamol, terbutaline, rimiterol, fenoterol, reproterol, adrenaline, pirbuterol, isoprenaline, orciprenaline, bitolterol, salmeterol,

formoterol, clenbuterol, procaterol, broxaterol, picumeterol, [TA-2005,] mabuterol, ipratropium bromide, beclomethasone, fluticasone, budesonide, tiptredane, dexamethasone, betamethasone, fluocinolone, triamcinolone acetonide, mometasone, and pharmacologically acceptable esters and salts thereof.

64. (Amended) A pharmaceutical aerosol formulation as claimed in claim 46, [including another pharmaceutically active agent] further comprising a substance selected from the group consisting of adjuvants, carriers, flavouring agents, buffers, antioxidants and chemical stabilisers.

77. (Amended) The method of claim 76, wherein [said propellant] the formulation comprises a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane (P134a), 1,1,1,2,3,3,3-heptafluoropropane (P227), [or] and 1,1-difluoroethane (P152a).

80. (Amended) The method of claim 76, wherein the surfactant is selected from the group consisting of an alkyl glucoside [or] and an alkyl maltoside.

81. (Amended) The method of claim 76, wherein the medicament is selected from the group consisting of a β 2-adrenoreceptor agonist, an anticholinergic bronchodilator, [or] and a glucocorticosteroid.